

Titan Pharmaceuticals, Inc. (TTNP-NASDAQ)

First Internal Sales of Probuphine

Based on our DCF model and a 15% discount rate, TTNP is valued at approximately \$8.50 per share based on contributions from Probuphine and ropinirole in the US/EU. We currently do not include any contribution from the triiodothyronine or other in-development programs. Valuation for pre-clinical programs will be added upon commencement of clinical trials.

Current Price (8/22/18) **\$0.78**
Valuation **\$8.50**

OUTLOOK

Titan Pharmaceuticals first launched its product, Probuphine, with a partner; however, due to poor sales Titan will now commercialize the implant with internal resources. The company is obtaining approval in Europe and has obtained approval in Canada, partnering to commercialize Probuphine in these and other regions.

Ropinirole is in clinical trials and several other candidates are about to enter the clinical phase of the development pipeline. All products use Titan's proprietary ProNeura drug delivery system. Consisting of ethylene-vinyl acetate and a drug substance, ProNeura is a novel approach to drug delivery that benefits from long-duration slow release and has characteristics beneficial to controlled substance programs.

Titan's development products include a treatment for Parkinson's Disease (ropinirole) and hypothyroidism (T3). The company is also working on a variety of other implants both in-house and with partners.

SUMMARY DATA

52-Week High **\$2.85**
52-Week Low **\$0.60**
One-Year Return (%) **-46.2**
Beta **1.39**
Average Daily Volume (sh) **74,620**

Shares Outstanding (mil) **21.2**
Market Capitalization (\$mil) **\$16.7**
Short Interest Ratio (days) **7.32**
Institutional Ownership (%) **6.8**
Insider Ownership (%) **7.0**

Annual Cash Dividend **\$0.00**
Dividend Yield (%) **0.0**

5-Yr. Historical Growth Rates

Sales (%) **N/A**
Earnings Per Share (%) **N/A**
Dividend (%) **N/A**

P/E using TTM EPS **N/A**
P/E using 2018 Estimate **N/A**
P/E using 2019 Estimate **N/A**

Zacks Rank **N/A**

Risk Level **Above Average**
Type of Stock **Small-Growth**
Industry **Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue (in millions of \$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	\$0.0 A	\$0.1 A	\$0.0 A	\$0.1 A	\$0.2 A
2018	\$1.1 A	\$2.7 A	\$0.1 E	\$0.1 E	\$1.4 E
2019					\$9.5 E
2020					\$18.1 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-\$0.14 A	-\$0.16 A	-\$0.20 A	-\$0.17 A	-\$0.68 A
2018	-\$0.12 A	-\$0.04 A	-\$0.13 E	-\$0.12 E	-\$0.53 E
2019					-\$0.19 E
2020					\$0.12 E

WHAT'S NEW

Second Quarter 2018 Financial and Operational Results

Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) [reported](#) second quarter 2018 results in its August 14th release and subsequently filed the supporting [10-Q](#) with the SEC. In the second quarter, Titan reported total revenues of \$2.7 million compared to \$77 thousand in 2Q:17. This amount consisted of \$500,000 amortized deferred revenue related to the sale of intellectual property rights to Molteni, \$7,000 of royalties from Braeburn, \$2.1 million related to the termination of the license agreement with Braeburn and \$75,000 in product sales of Probuphine by Titan. It is this last revenue item which we are most excited about as it indicates that the internal sales process is working and product is being moved to providers through the Titan channel.

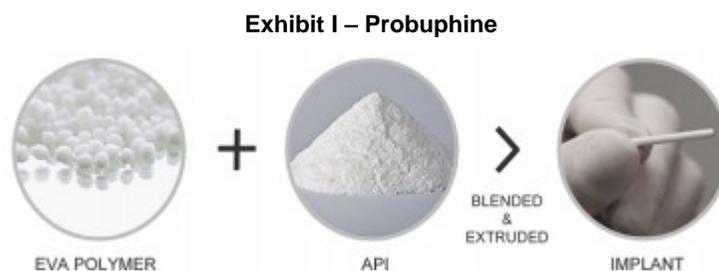
The \$75,000 in sales represents the partial period between May 25, 2018 when the licenses were returned and the end of the quarter June 30. Grossed up to a full quarter basis, sales would have been ~\$190,000.

Total expenses of \$3.3 million include \$70,000 in cost of goods sold, \$1.9 million of R&D and \$1.4 million of G&A. R&D costs fell 26% while G&A rose 15%. Lower R&D was attributable to decrease in external R&D efforts for ropinirole, while higher G&A stemmed from greater employee, legal and professional fees.

Cash and equivalents as of June 30, 2018 were \$1.6 million, compared to \$7.5 million at the end of 2017. Debt was \$3.5 million. Subsequent to the end of the quarter, there was an amendment to the purchase agreement with Molteni which provided \$1.1 million (€950,000) on August 3, 2018. There is an additional \$0.6 million in a convertible loan also from Molteni that is expected next month. Additionally, an S-1 was filed on August 14 in preparation to raise sufficient funds from equity and convertible securities to fund the internal commercialization of Probuphine. Cash burn was (\$1.9) million in 2Q:18 compared to (\$2.5) million in 2Q:17.

Return of Probuphine

Titan [announced](#) on January 22 that it was in discussions with Probuphine license holder Braeburn regarding the disposition of Probuphine. Sales of the implant had been disappointing since the 2Q:16 launch of the product as Braeburn worked through payor, reimbursement, and Risk Evaluation and Mitigation Strategy (REMS) requirements among other complexities since first sales. Due to the shift of Braeburn management's attention toward addressing the CRL, a transfer of the development license from Braeburn emerged as the most efficient path forward.



On May 25, 2018, rights were transferred back to Titan, and the company began commercialization activities immediately, using the existing Braeburn sales team, based on our reading of the filings (Titan is currently in a quiet period). Additionally, Braeburn transferred \$1 million in cash and inventory worth \$1.1 million along with support services through the end of 2018. Titan was also assigned the sublicense agreement with Knight Therapeutics (TSE: GUD) who has secured regulatory approval to commercialize Probuphine from Health Canada. Knight expects a fourth quarter 2018 launch.

Exhibit II – Titan Pipeline

CANDIDATE	INDICATION	STAGE				
Probuphine (United States)	Opioid Use Disorder	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET
Probuphine (European Union)	Opioid Use Disorder	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET
Ropinirole Implant	Parkinson's Disease	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET

August 2018 S-1

Titan has outlined a strategy to build a small sales and marketing team to commercialize Probuphine as a specialty product. This objective will require additional capital to hire, train and dispatch sales representatives into the targeted markets. To achieve this objective, Titan filed an [S-1](#) on August 14, 2018 that is seeking to raise capital from equity and convertible bond issuance of approximately \$15 million. The estimated proceeds from the issuance are expected to be sufficient to fund the internal commercialization efforts for Probuphine and the FDA-required Phase IV studies¹ through 2019.

Following the filing of the S-1, Titan has entered into a quiet period after which we expect to have additional information on the composition of and strategy for the salesforce.

Marketing Strategy

Titan has outlined its internal marketing strategy after receiving the rights back to commercialize Probuphine in the United States. The company has been in the process of transitioning all of the Probuphine commercialization activities from Braeburn to Titan, including supply chain, logistics, medical affairs, REMS, training and reporting. Titan will pursue a targeted strategy that will employ a small 10 person commercial team that will target four market segments:

- High Probuphine-prescribing physicians with long term recovery oriented treatment programs.
 - Contact information already in database
 - Establish centers of excellence to generate referrals
 - Focus on reduction of complexity for supply chain and reimbursement
 - 90% of buprenorphine certified providers written by 6,000 providers²
- Residential treatment facilities
 - Establish partnership with a few large programs
- Academic institutions with addiction treatment and training programs
 - Providers are trained in the use of this class of therapy
 - Introduce Probuphine to next generation of providers
 - Develop KOLs who can disseminate the benefits of the therapy more widely
 - Generate additional investigator sponsored studies
- Criminal justice system
 - Provide help to high recidivism population
 - Initial focus on a few key programs with success to drive wider adoption
 - Almost 60 million incarcerated suffer from opioid use disorder³

¹ As a condition of the marketing approval for Probuphine, the FDA required three postapproval Phase IV clinical trials to assess potential safety risks associated with the insertion and removal of Probuphine, potential prolongation of the QT interval and to assess the potential for repeat administration of Probuphine into the same insertion site or insertion into an alternate site.

² Management cited numbers

³ Management cited numbers

Exhibit III – Segmentation Strategy



Since the release of the quarterly report, Titan has updated shareholders on their commercialization initiatives with a [collaboration](#) with the Nevada Center for Behavioral Health. This collaboration will evaluate the use of Probuphine to treat opioid use disorder (OUD) patients in the Nevada criminal justice system. It is a pilot program and includes the training and certification of seven health care providers regarding the Probuphine Risk Evaluation and Mitigation Strategy (REMS). A grant related to the 21st Century Cures Act was provided from state and federal authorities to fund the work. The incarcerated market for OUD in the United States is large. Titan statistics estimate that about a quarter of the 2.3 million confined persons in the U.S. suffer from OUD; however, less than 1% are given access to medications for it. The hesitation to use the opioid-based treatments is due to concerns over diversion, which does occur with sublingual formulations. Given Probuphine's ability to avoid diversion, it is a particularly attractive alternative in this setting. The focus on this population is supported by a [study](#) in Rhode Island that showed a 61% decrease in post-incarceration deaths and a 12% reduction in statewide overdose deaths a year following the implementation of a treatment program for incarcerated addicts.

We expect that success in each of the targeted areas will lead to wider adoption over time.

NASDAQ Notices

On April 9, 2018 the Nasdaq notified Titan that they were not in compliance with exchange listing requirements as they did not maintain minimum stockholders' equity requirements. In response, the company submitted a plan of compliance and was granted an extension to October 8, 2018. On August 15, 2018, Titan received a notification that shares were not in compliance with minimum bid requirements and that they must regain compliance by February 11, 2019.

Clarification of Knight Relationship

Knight was originally partnered with Braeburn to obtain regulatory approval and commercialization of Probuphine in Canada. However, as a result of the dissolution of the agreement between Titan and Braeburn, the relationship with Knight was unclear. However, during the transition the agreement with Knight was amended in August 2018 where Titan granted the Canadian partner and exclusive license to commercialize Probuphine in Canada. As a result of the agreement, Titan is entitled to receive royalty payments from Knight from the low teens to the low 30% range and they will be the exclusive provider of product to Knight. In April of 2018, Knight announced that regulatory approval of Probuphine had been granted by Health Canada. Knight expects to launch Probuphine by the end of 2018 as indicated in their August 9th quarterly update.

Molteni Agreement

On August 3rd, Titan [amended](#) its agreement with Molteni forfeiting €2.0 million regulatory milestones for the certainty of €950,000 on the date of the amendment to support short term capital needs. The amendment also includes a convertible loan of €550,000. Below we provide a timeline of interactions with Molteni.

- March 21, 2018 – Asset purchase, supply & support agreement with Titan
 - €2.0 million received for purchased assets
 - Aggregate of €1.0 million of milestone payments subject to limitations
 - Earn out payments for up to 15 years (low teens to mid-20% range royalty)
 - Titan supplies semi-finished product
- Amended loan agreement with Molteni
 - Molteni assumed \$2.4 million of Horizon loan
 - Gains equity conversion rights
- August 3, 2018 – Amendment of asset purchase, supply & support agreement with Titan
 - €550,000 convertible loan
 - €950,000 on execution of amendment
 - €2.0 million regulatory milestones waived

Pipeline and Marketed Products

- Probuphine North America
 - Titan and Braeburn completed return of commercialization rights
 - New targeted plan for commercialization
- Probuphine Europe
 - November 6, 2017 filing of MAA
 - Addressing questions from the EMA with response submission expected in Fall 2018
 - Notice of Allowance from European Patent office for methods of use providing protection until 2023
- Ropinirole
 - First patient treated early October 2017
 - Independent Data Safety Monitoring Board to review initial data June 2018
 - Program on hold until additional capital available
- Triiodothyronine (T3)
 - Completing non-clinical evaluation of its re-formulated implant
 - Pre-IND review with the FDA anticipated
- New Candidates being evaluated for ProNeura
 - Opioid antagonist collaboration with Opiant Pharmaceuticals
 - Prevention of opioid relapse and overdose in individuals with opioid use disorder
 - Targeting completion of feasibility assessment in 1H:18
 - Tenofovir and emtricitabine for pre-exposure prophylaxis against HIV acquisition
 - Anti-malarial agents
 - Entered into Cooperative Research and Development Agreement with Reed Army Institute of Research (WRAIR) and Southwest Research Institute (SwRI)
 - Walter Reed pursuing funding opportunities for the program
 - κ -opioid receptor as non-opioid analgesic for chronic pain
 - Liraglutide for Type 2 diabetes
 - Liothyronine (LT3) for treatment of hypothyroidism
 - Oxytocin for autism spectrum disorder

Other Achievements

- Return of Braeburn License and first internal sales of Probuphine – May 25, 2018
- New Members Added to Board of Directors
 - Federico Seghi Recli, formerly CEO of Molteni
 - Scott Smith, formerly COO of Celgene
 - Dr. Rajinder Kumar, CEO of MeRaD Pharmaceutical Ltd

Summary

Bringing Probuphine back under company control starts a new chapter for Titan Pharmaceuticals. The buprenorphine implant failed to gain any traction under Braeburn's direction, and we are hopeful that Titan's thoughtful and focused strategy will be able to address and overcome the difficulties faced by their commercialization predecessor. We are optimistic that early success with the Nevada Center for Behavioral Health is a prelude for additional collaborations. Titan's strategy of hiring a small salesforce and targeting high impact channels appears to be capital efficient and also may ease some of the difficulties suffered by Braeburn, such as REMS compliance and reimbursement difficulties. The loss of control over and poor execution by its former partner has motivated the company to directly manage the commercialization process and it is now raising capital to execute on its commercialization plan. We maintain our valuation at \$8.50 per share based on the potential for Probuphine and probability adjusted valuation for Ropinirole implant.

PROJECTED FINANCIALS

Titan Pharmaceuticals, Inc. - Income Statement

Titan Pharmaceuticals, Inc.	2017 A	Q1 A	Q2 A	Q3 E	Q4 E	2018 E	2019 E	2020 E
Total Revenues	\$0.2	\$1.1	\$2.7	\$0.1	\$0.1	\$3.9	\$9.5	\$18.1
<i>YOY Growth</i>	-98.6%	2560.0%	3364.9%	150.0%	72.4%	1728.8%	140.5%	91.1%
R&D	\$9.6	\$1.9	\$1.9	\$2.5	\$2.3	\$8.5	\$9.0	\$7.2
G&A	\$5.1	\$1.6	\$1.4	\$1.7	\$1.7	\$6.3	\$6.8	\$6.8
Operating Income	(\$14.5)	(\$2.4)	(\$0.6)	(\$4.1)	(\$3.9)	(\$11.0)	(\$6.3)	\$4.1
<i>Operating Margin</i>	-6745.1%	-	-	-	-	-278.6%	-67.1%	22.5%
Total Other Income	\$0.0	(\$0.2)	(\$0.2)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Pre-Tax Income	(\$14.5)	(\$2.6)	(\$0.9)	(\$4.1)	(\$3.4)	(\$11.0)	(\$6.3)	\$4.1
Taxes & Other	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	(\$14.5)	(\$2.6)	(\$0.9)	(\$4.1)	(\$3.4)	(\$11.0)	(\$6.3)	\$4.1
<i>Net Margin</i>	-	-	-	-	-	-	-	-
Reported EPS	(\$0.68)	(\$0.12)	(\$0.04)	(\$0.13)	(\$0.11)	(\$0.42)	(\$0.19)	\$0.12
<i>YOY Growth</i>	-385.8%	-12.6%	-74.8%	-34.3%	-36.5%	-38.9%	-54.0%	-160.4%
Weight Ave. Shares Out	21.2	21.2	21.2	31.2	31.3	26.2	33.0	35.0

Source: Company Filing // Zacks Investment Research, Inc. Estimates

HISTORICAL STOCK PRICE

Titan Pharmaceuticals, Inc. – Share Price Chart



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